

written statements may be submitted for the record. Members of the public also may submit written statements for distribution to the MCSWG membership and inclusion in the public record without presenting oral statements. Such written statements should be sent to the MCSWG Executive Director, as shown above, by mail or fax at least five business days before the meeting.

Minutes of all public meetings and other documents made available to the MCSWG will be available for public inspection and copying at both the DOL and DHHS. At DHHS, these documents will be available at the MCSWG Executive Director's Office, Office of Child Support Enforcement (OCSE), Administration for Children and Families, U.S. Department of Health and Human Services, Aerospace Building, Fourth Floor—East, 370 L'Enfant Promenade, SW, Washington, DC from 8:30 a.m. to 5:30 p.m. Questions regarding the availability of documents from DHHS should be directed to Andrew J. Hagan, OCSE (telephone (202) 401-5375). This is not a toll-free number. Any written comments on the minutes should be directed to Ms. Samara Weinstein, Executive Director of the Working Groups, as shown above.

Dated: July 26, 1999.

**David Gray Ross,**

*Commissioner, Office of Child Support Enforcement.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Reallotment of Funds for FY 1998 Low Income Home Energy Assistance Program (LIHEAP)

**AGENCY:** Office of Community Services, ACF, DHHS.

**ACTION:** Notice of determination concerning funds available for reallotment.

**SUMMARY:** In accordance with section 2607(b)(1) of the Omnibus Budget Reconciliation Act of 1981 (42 U.S.C. 8621 *et seq.*), as amended, a notice was published in the **Federal Register** on June 8, 1999 announcing the Secretary's preliminary determination that \$2,381,450.52 in FY 1998 Low Income Home Energy Assistance Program (LIHEAP) funds may be available for reallotment to other LIHEAP grantees. We received a comment from one of the grantees with excess carryover funds indicating that a further review of

records revealed that the amount of funds available for reallotment is reduced by \$172,597. No additional comments were received. Therefore, the amount of funds available for reallotment is \$2,208,853.52.

It has now been determined that the funds will be reallotted to all LIHEAP grantees based on the normal allocation formula. No subgrantees or other entities may apply for these funds.

**FOR FURTHER INFORMATION CONTACT:**

Janet Fox, Director, Division of Energy Assistance, Office of Community Services, 370 L'Enfant Promenade, SW, Washington, DC 20447; telephone number (202) 401-9351.

Dated: July 27, 1999.

**Donald Sykes,**

*Director, Office of Community Services.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 97P-0350]

#### Obstetrics and Gynecology Devices; Reclassification of Home Uterine Activity Monitor

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of panel recommendation.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing for public comment the recommendation of the Obstetrics and Gynecology Devices Panel (the Panel) to reclassify the home uterine activity monitor (HUAM) from class III to class II. The Panel made this recommendation after reviewing the reclassification petition submitted by Corometrics Medical Systems, Inc., and other publicly available information. FDA also is announcing for public comment its tentative findings on the Panel's recommendation. After considering any public comments on the Panel's recommendation and FDA's tentative findings, FDA will approve or deny the reclassification petition by order in the form of a letter to the petitioner. FDA's decision on the reclassification petition will be announced in the **Federal Register**. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a guidance document that provides 510(k) applicants with specific directions regarding data and information that should be submitted to FDA in 510(k) submissions for HUAM's. **DATES:** Written comments by October 28, 1999.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

Colin M. Pollard, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1180.

**SUPPLEMENTARY INFORMATION:**

#### I. Background (Regulatory Authorities)

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94-295), the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101-629), and the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105-115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines